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| 09/712,795 | 11/14/2000 | Harold G. Craighead | 1153.010US1 | 8906 |

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EXAMINER

CHEU, CHANGHWA J

| | |
|----------|----------------|
| ART UNIT | - PAPER NUMBER |
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1641

DATE MAILED: 03/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/712,795

Applicant(s)

CRAIGHEAD ET AL.

Examiner

Jacob Cheu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 December 2004.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 8-24 and 27-61 is/are pending in the application.
4a) Of the above claim(s) 27-61 is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 1-6 and 8-24 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____

DETAILED ACTION

Applicant's amendment filed on 12/20/2004 has been received and entered into record and considered.

The following information provided in the amendment affects the instant application:

1. Claims 7, 25 and 26 are cancelled.
2. Currently, claims 1-6, 8-24 are under examination. Claims 27-61 are withdrawn from further consideration.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

2. Claims 1-6, 8-11, 21-23, are rejected under 35 U.S.C. 102(e) as being anticipated by Quate et al. (US 6436647).

Quate et al. teach a sensor comprising microcantilevers to detect analytes in a sample. Quate et al. teach that immobilized binding partners, i.e. DNA sequence, on the tips of the cantilever fingers to bind to the target analytes where the binding can change the

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resonant frequency of the cantilever (Figure 1 and 2; Col. 4, line 10-22; claim 12). Quate et al. teach that several physical characteristics, including induced stress, heat, or *change in mass*, can be used to detect the presence of the analyte by this microcantilever device (See Abstract, Col. 4, line 12-20; claim 12)(emphasis added).

With respect to claims 2-5, Quate et al. also use detectors, such as split photodiode, lineary array of photdetectors, piezoresistance detectors to detect the binding signals (Col. 5, line 55-60).

The cantilevers taught by Quate et al. contain immobilized portion and a second portion, i.e. tip finger, for binding partner immobilization (See Figure 1 and 2).

With respect to claim 8, the material for the device can be of silicon (Col. 2, line 16-25).

With respect to claims 9-11, the cantilever device can be used to detect analyte binding caused by thermal change (See claim 12).

With respect to claim 21, Quate et al. disclose that the cantilever device can also be used in detection of DNA, protein array and polypeptide arrays (Col. 7, claims 7 and 8).

3. Claims 1-6, 8-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Grey et al. (US 20030154771).

Grey et al. teach teach a sensor comprising microcantilevers to detect analytes in a sample. Grey et al. teach that immobilized binding partners, i.e. antigen or antibody, on the tips of the cantilever fingers to bind to the target analytes where the binding can change the resonant frequency of the cantilever (See Section 0216). Grey et al. teach that several physical characteristics, including induced stress, heat, or *change in mass*, can be used to detect the presence of the analyte by this microcantilever device (See Section

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0009-0010)(emphasis added). The change of the frequency can be detected by laser light beam (See Section 0008).

With respect to claims 2-6, Grey et al. teach using photodetector for determining the change of mass of the analyte by the resonant frequency (See Section 0009-0013).

With respect to claim 8, Grey et al. teach that the micricantilever can be made of silicon or silicon nitride (See Section 0008).

With respect to claim 10, Grey et al. teach that the cantilever is adapted for vibration under thermal condition (See Section 0033, 0104).

With respect to claim 11 and 13, Grey et al. teach that the microcantilever can be operated under ambient or vacuum condition (See Section 0102).

With respect to claim 12, Grey et al. teach that the microcantilever can be coupled to a piezoelectric drive (See Section 0072 and 0082).

With respect to claims 14-21, Grey et al. teach that the microcantilever device can be used to detect DNA fragments, proteins, microorganisms and cells (See Section 0005).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 14-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quate et al..

Quate et al. reference has been discussed but is silent in teaching use the said microcantilever to detect cells, such as pathogen, virus or antibody, ligand or receptor.

Although the device of Quate et al. is particularly useful in determining DNA hybridization, Quate et al. teach that the application is not limited merely to DNA detection. Quate et al. teach that the principle of the microcantilever can be applied to any chemical interactions of analytes, including polypeptides, protein, carbohydrate, hydrogen bond, hydrophobic, electrostatic, or DNA hybridization (See Abstract, Col. 4, line 12-20; claims 1-9, 22-23). Therefore it would have been obvious to one ordinary skill in the art at the time the invention was made to have applied the device of Quate et al. to detect microorganisms, receptor or antibody with reasonable expectation of success since the interactions of receptor-ligand as well as antibody-antigen are mainly based on protein-protein or polypeptide-epitopes interactions, or hydrophobicity attachment, and in general cellular surface contains abundant carbohydrates and protein antigens.

7. Claims 24 is rejected under 35 U.S.C. 103(a) as being unpatentable over Quate et al. or Grey et al. in view of Chan et al. (US 6124765).

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Both Quate et al. and Grey et al. references have been discussed but are silent in teaching a cantilever beam with the length of 0.5 to 1000 micron. Chan et al. disclose that varying the length of cantilever beam can have effects on the resonant frequency on the cantilever (See Figure 8-11). The length of cantilever beam ranging from 0-100 micron which falls within the recited range as in claim 24. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided Quate or Grey et al. with the optimal length of cantilever beam for a better result with different analytes since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Applicant's Arguments

8. The rejections of claims 1-4, 6-9, 11-21 under 35 U.S.C. 102(b) as being anticipated by Ebersole et al. (US 5756279) are withdrawn.
9. The rejections of claims 1-6, 8-11, 21-23 under 35 U.S.C. 102(e) as being anticipated by Quate et al. (US 6436647) are maintained.
10. The rejection of claims 24 under 35 U.S.C. 103(a) as being unpatentable over Quate et al. in view of Davis et al. (US 6311557) is withdrawn.

Quate et al. reference

Applicant argues that Quate et al. reference does not teach the instant invention device. Applicant argues that Quate et al. does not disclose a resonant device by measuring the resonant frequency shift corresponding to the change of mass as recited in claim 1. Applicant's arguments have been considered but are not persuasive. As indicated in this Office Action, Quate et al. teach that "[a] physical or chemical change might also result in a change in mass on the cantilever. In such an example, the resonant frequency of the cantilever will change due to the mass change. Measuring the resonant frequency of the cantilever under such circumstances

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will allow the physical or chemical change to be detected' (See Col. 4, line 12-20)(emphasis added). Therefore, the teachings of Quate et al. is clearly with the recited feature. Accordingly, Quate et al. device anticipates the current invention.

Conclusion

11. No claim is allowed.

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jacob Cheu whose telephone number is 571-282-0814. The examiner can normally be reached on 9:00-5:00.

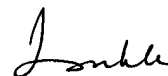
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Jacob Cheu
Examiner
Art Unit 1641



March 5, 2005



LONG V. LE
SUPERVISORY PATENT EXAMINER
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03/07/05